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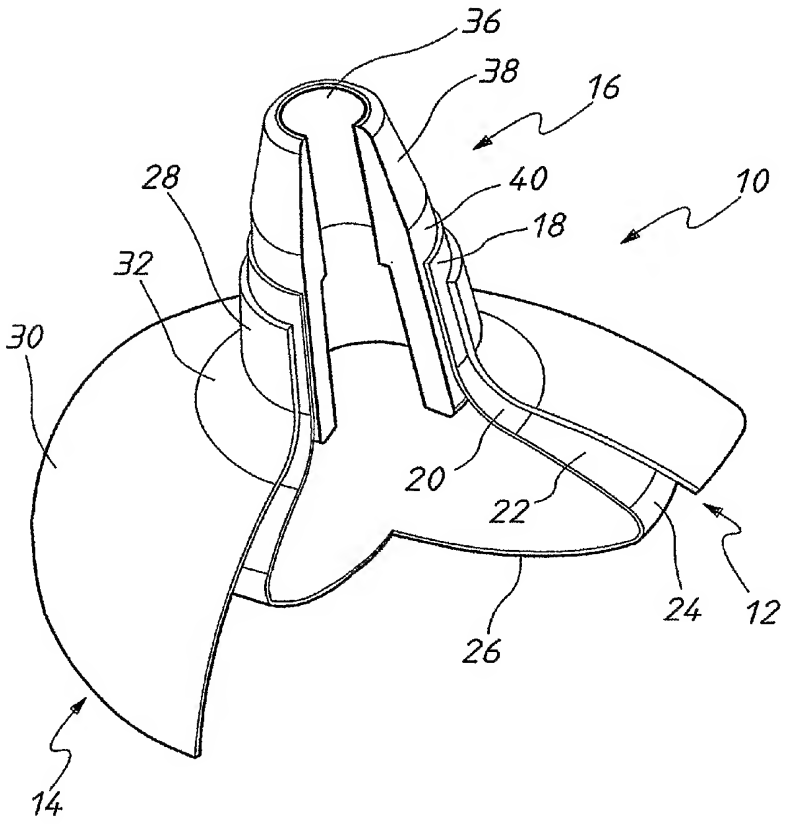
(54) Title: ACTUATOR FOR A HEART ASSIST DEVICE



(57) Abstract: An actuator (10) for a heart assist device. The actuator (10) includes an inflatable balloon (12) and a shroud or wrap (14). The inflatable balloon (12) has a first body portion (22), a second body portion (26) and a flexure regionjoining (24) the first (22) and second (26) body portions. The shroud or wrap, (14) is positioned adjacent the first body portion (24) and has a peripheral extent at least equal to, the peripheral extent of the balloon flexure region (24). The balloon (12) and the shroud or wrap (14) are shaped such that the shroud or wrap (14) restrains a part of the balloon first body portion (22) at or near the flexure region (24) against displacement towards the shroud or wrap (outward displacement) past a predetennined limit but allows unrestrained displacement away from the shroud or wrap (inward displacement).

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Actuator for a heart assist device

Field of the Invention

The present invention relates generally to heart assist devices, systems and methods and, more particularly, to an actuator for a counter-pulsation heart assist device.

Background of the Invention

US Patent No. 4630597 and International PCT Patent Application No. PCT/US00/22992 (WO 01/13974) both disclose heart assist devices that utilise an inflatable balloon that is positioned within an arterial vessel of a patient. The balloons replace a resected portion of the vessel and are cyclically inflated and deflated to expand into the vessel and thus assist in blood displacement during diastole and retract from within the vessel during systole.

Both of the above documents disclose devices that have a relatively rigid shell with an inlet/outlet port which is connected to a fluid pump. The flexible balloon seals around the periphery of the shell and extends back over the shell for some or all of its exterior. Another layer of material is then placed over the balloon exterior, adjacent the shell, to secure the balloon to the shell.

The Applicant's International PCT Patent Application No's. PCT/AU00/00654, PCT/AU01/01187, and PCT/AU02/00974 all disclose actuators that were found to fail due to fatigue in the balloon interfacing with the aorta.

It is an object of the present invention to provide an improved actuator.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides an actuator for a heart assist device, the actuator including:

an inflatable balloon having a first body portion, a second body portion and a flexure region joining the first and second body portions; and

a shroud or wrap adjacent the first body portion and having a peripheral extent at least equal to the peripheral extent of the balloon flexure region;

wherein the balloon and the shroud or wrap are shaped such that the shroud or wrap restrains a part of the balloon first body portion at or near the flexure region against displacement towards the shroud or wrap (outward displacement) past a predetermined limit but allows unrestrained displacement away from the shroud or wrap (inward displacement).

The balloon and the shroud are preferably shaped such that the shroud restrains said part of the balloon first body portion at or near the flexure region against outward displacement during inflation of the balloon but allows unrestrained inward displacement during deflation.

Preferably, during inward displacement, at least part of the inner surface of the balloon second body portion is able to be drawn against at least part of the inner surface of the balloon first body portion.

The shroud is preferably generally inwardly concave, most preferably elongated, and elliptical.

The first body portion, second body portion and flexure region are preferably integrally formed, most preferably by dip moulding.

The actuator preferably also includes a bushing adapted for connection to a motive power source.

The balloon preferably also includes a neck portion joined to the first portion, the neck portion being adapted for sealing connection with the bushing.

The shroud preferably also includes a neck portion adapted for sealing connection with the balloon neck portion.

In a second aspect, the present invention provides an actuator for a heart assist device, the actuator including:

a bushing adapted for connection to a hydraulic or pneumatic power source; and

an inflatable balloon having a narrower neck portion adapted for sealing connection with the bushing exterior, wider first and second body portions and an arcuate flexure region joining the first and second body portions, the first body portion having a first end adjacent the neck portion and a second end adjacent the second body portion and being generally inwardly concave, the second body portion being inwardly concave when the balloon is inflated and generally outwardly concave when the balloon is deflated.

The device preferably also includes a shroud or wrap having a body portion with a peripheral extent at least equal to the peripheral extent of the balloon first and second body portions.

The balloon and the shroud or wrap are preferably shaped such that a part of the balloon first body portion at or near the flexure region is restrained against outward displacement past a predetermined limit by the shroud or wrap but unrestrained against inward displacement.

Preferably, during inward displacement, at least part of the inner surface of the balloon second body portion is able to be drawn directly against at least part of the inner surface of the balloon first body portion.

In a third aspect, the present invention provides a heart assist device including:

a hydraulic or pneumatic power source; and

an actuator including:

a bushing adapted for operative connection to the motive power source;

an inflatable balloon having a narrower neck portion adapted for sealing connection with the bushing exterior, wider first and second body portions and a flexure region joining the first and second body portions, the first body portion having a first end adjacent the neck portion and a second end adjacent the second body portion and being generally inwardly concave, the second body portion being generally inwardly concave when the balloon is inflated and generally outwardly concave when the balloon is deflated; and

a shroud or wrap having a body portion with a peripheral extent at least equal to the peripheral extent of the balloon first and second body portions,

wherein the balloon and the shroud are shaped such that a part of the balloon first body portion at or near the flexure region is restrained against outward displacement by the shroud past a predetermined limit but unrestrained against inward displacement.

Preferably, during inward displacement, at least part of the inner surface of the balloon second body portion is able to be drawn against at least part of the inner surface of the balloon first body portion.

Preferably, the balloon and shroud are shaped such that substantially all of the balloon first body portion is restrained against outward displacement by the shroud and unrestrained against inward displacement.

In its preferred form, the heart assist device is configured for extra-aortic counter-pulsation. In this form, the balloon is positioned on the exterior of an arterial vessel.

In a further form, the heart assist device is configured for use either as an interposition graft in which the device replaces a completely resected section of the aorta or as an aortic patch in which an aperture is formed in the aorta which is filled with the device.

When the balloon is inflated, the flexure region preferably has a radius of curvature of at least 0.1 mm, more preferably a radius of curvature of approximately 1.0 mm and most preferably a radius of curvature of approximately 3.0 mm.

The ratio of the diameter of the balloon neck portion to the balloon flexure region is preferably no more than approximately 4:1, and more preferably approximately 3:1 and most preferably approximately 2:1.

The bushing preferably has an inlet/outlet bore. The bore preferably also includes one or more internal restrictions adapted to prevent suction of the balloon into the bore.

The balloon is preferably formed from silicone, polyurethane or a polyurethane-polysiloxane block co-polymer. The balloon is preferably formed by mandrel dipping. The balloon is preferably formed by dipping a suitably shaped mandrel into the polymer and allowing a thin coating of the polymer to cure on the mandrel. The balloon is preferably made of 2 to 4 coatings, with a total thickness of 150-300 microns. The balloon can then be removed from the mandrel.

The balloon neck portion is preferably a snug sealing fit over the bushing exterior. The shroud or wrap preferably has a neck portion that is a snug sealing fit over the balloon neck portion.

The bushing preferably has a slightly tapered neck portion adapted for engagement with the balloon neck portion. The bushing neck portion preferably has a converging taper in the direction of the balloon.

The balloon is preferably held in place on the aorta by a flexible wrap which extends about the aorta and bears against the first body portion of the balloon or a shroud mounted thereon. The wrap is preferably shaped to fit the second body portion of the balloon, and if desired also the neck portion. The wrap is preferably inelastic or slightly elastic so that its stretch and flexibility characteristics substantially match those of the native aorta.

In a fourth aspect, the present invention provides a flexible inflatable balloon for a blood displacing heart assist device, the balloon including:

a neck portion having first and second ends;

a substantially annular first body portion connected at its inner periphery to the neck portion second end; and

a substantially oval or circular second body portion connected at its outer periphery to the outer periphery of the first body portion,

the outer peripheries of the first and second body portions are connected along an annular inwardly concavely curved flexure portion adapted to maintain a radius of curvature during movement of the second body portion between inwardly concave and outwardly concave during deflation and inflation of the balloon respectively.

The balloon is advantageously formed as a single piece. This avoids the presence of a seam line as is disclosed in US Patent specification 4,630,597 or International patent specification WO 01/13974. Such seam lines have been found by the present inventors to raise stress levels in the balloon and reduce the operational life of the balloon.

A shroud can be provided to overlie and abut the annular first body portion of the balloon. The shroud is preferably shaped such that the shroud restrains said portion of the balloon at or near the flexure region against outward displacement during inflation of the balloon but allows unrestrained inward displacement during deflation. The shroud is preferably generally inwardly concave, most preferably elongated, and elliptical. The shroud preferably also includes a neck portion adapted for sealing connection with the balloon neck portion. The shroud may act to facilitate bonding a wrap to the first body portion of the balloon.

The balloon preferably also includes a bushing adapted for connection to a hydraulic or pneumatic power source. The bushing also acts to prevent inward collapse of the balloon neck portion during deflation. If desired the bushing can be formed with internal restrictions such as flutes, ribs or secondary lumens to prevent the balloon being sucked into the bushing during deflation of the balloon. The neck portion of the balloon is preferably adapted for sealing connection with the bushing. The bushing preferably has a taper adapting the relatively large diameter of the neck of the balloon to the relatively small diameter of a hydraulic or pneumatic fluid line connecting the balloon to a power source. This taper is preferably elongated to enhance the flexibility of the bushing along its central axis.

In a fifth aspect, the present invention provides an actuator for a heart assist device, the actuator including:

a flexible inflatable balloon having a neck portion connected at one end to a bulbous body portion having a first side and a second side; and

a substantially inelastic shroud or wrap having a flared portion that extends over the adjacent first side of the balloon bulbous portion,

wherein, during deflation, the second side of the bulbous body portion is able to be drawn against the first side of the bulbous body portion.

The shroud or wrap preferably supports the first side of the balloon bulbous portion against substantial movement whilst the second side of the balloon bulbous portion is free to move during inflation and deflation.

In a sixth aspect, the present invention provides a method of providing extra-aortic heart assistance using the actuator of the first or the second or the fifth aspect or the heart assist device according to the third aspect or the balloon of the fourth aspect, the method including mounting the balloon second body portion adjacent the exterior of an arterial vessel.

In a seventh aspect, the present invention provides a method of providing intra-aortic heart assistance using the actuator according to the first or the second or the fifth aspect or the heart assist device according to the third aspect, the method including resecting a portion of an arterial vessel and mounting the balloon with the balloon second body portion sealingly replacing the resected arterial portion.

Brief Description of the Drawings

Preferred embodiments of the invention will now be described, by way of examples only, with reference to the accompanying drawings in which:

Fig. 1 is an exploded perspective view of a first embodiment of an actuator according to the invention;

Fig. 2 is an assembled, partial cut away, perspective view of the actuator shown in Fig. 1;

Fig. 3 is an assembled, cross sectional view of the actuator shown in Fig. 1 along the line 3-3;

Fig. 4 is an assembled, cross sectional view of the actuator shown in Fig. 1 along the line 4-4;

Fig. 5 is a cross sectional view of the second embodiment of an actuator according to the invention along the line 5-5;

Fig. 6 is an underside view of the bushing used in the actuator shown in Fig. 5;

Fig. 7 is a cut away perspective view of a balloon for a third embodiment of an actuator according to the invention;

Fig. 8 is a top view of the balloon shown in Fig. 7;

Fig. 9 is a cut away side view of a fourth embodiment of an actuator according to the invention;

Fig. 10 is a perspective view of the actuator shown in Fig. 9; and

Fig. 11 is a front view of the actuator shown in Fig. 9.

Detailed Description of the Preferred Embodiments

Fig.1 shows an exploded perspective view of an actuator 10 according to a first embodiment of the present invention, which is sized for paediatric use. The actuator 10 has a flexible, inflatable balloon 12, an inelastic shroud 14, and a relatively rigid bushing 16.

The balloon 12 is formed from Polyurethane or similar biocompatible and biostable material by mandrel dipping. The balloon 12 has a narrower neck portion 18 which is connected by a flared part 20 to a wider first body portion 22. A flexure region 24, which extends generally around the exterior of the balloon 12 at its widest part connects a second body portion 26 (see Figs. 2 to 4) to the first body portion 22.

When viewed in plan, the first and second body portions are generally elliptical in shape and have a maximum width and length of about 20-35mm and 50-90mm respectively for adult sized balloons. The balloon neck portion has a diameter of approximately 10-14mm at its distal end 18a and, at its proximal end 18b, it is elliptical in shape with dimensions of approximately 30-50mm in the long axis and 15-30mm in the short axis of the balloon 12, and with a converging taper therebetween. Paediatric balloons are also considered in this same application, but scaled downward appropriately.

The shroud 14 is formed, by mandrel dipping, from a material substantially equivalent to the material used for the balloon, such as a Polyurethane or a Polyurethane-Polysiloxane block co-polymer. The shroud 14 has a narrower neck portion 28 which is joined to a wider body portion 30 by a flared part 32. The shroud body portion 30 is also generally elliptical in shape when viewed in plan and has a larger peripheral extent (ie extends further in all directions) than the balloon body portions 22 and 26 and flexure region 24. More particularly, the shroud body portion 30 has a length (along the long axis of the balloon 12) of 60-100mm and a minimum width of (across the short axis of the balloon 12) of 20 mm. The shroud neck portion 28 is sized to be a snug sealing fit over the exterior of the balloon neck portion 18.

The bushing 16 is formed, by injection moulding, from a flexible plastic such as Polyurethane or a similar material. The bushing 16 has a hollow bore 36 which is adapted

for sealing connection with a fluid line from a motive power source such as a fluid pump (not shown). Suitable pumps are disclosed in the Applicant's International PCT Patent Application No. PCT/AU02/00974 entitled "A fluid pressure generating means", the contents of which are hereby incorporated by cross reference. The bushing 16 also has a relatively more tapered distal part 38 and a relatively less tapered proximal part 40. The proximal part 40 is sized to be a snug sealing fit within the interior of the balloon neck portion 18.

Fig. 2 shows the device 10 after assembly. The assembly comprises initially stretching the neck portion 18 of the balloon 12 so that the proximal part 40 of the bushing 16 can be inserted therein. The balloon 12 is retained adjacent the bushing 16 by the shroud 14 being forced past the distal part 38 of the bushing 16 until it is a snug sealing fit on the exterior of the balloon neck portion 18 as shown. The bushing proximal part 40, the balloon neck portion 18, and the shroud neck portion 28 all have a common taper angle. The components are also bonded together with a suitable adhesive in order to ensure an effective seal therebetween.

The operation of the device 10 will now be described by with reference to Figs. 3 and 4. Fig. 3 is a cross-sectional (anterior) view along the longitudinal direction of the aorta. Fig. 4 is a partial cross-sectional view orientated at 90 degrees from that of Fig. 3.

For extra-aortic heart assistance, the device 10 is placed with the balloon second portion 26 adjacent the exterior of an arterial vessel, most preferably the outer part of the ascending aorta (not shown). A flexible, relatively inelastic wrap is placed over the shroud 30 and around the aorta in order to retain the device 10 in place. Wraps are well known in the art and thus will not be described in further detail. The wrap can also be used in place of the shroud.

In use, fluid is cyclically driven to and from the balloon 12, via the bushing bore 36, to cyclically inflate and deflate the balloon 12. The inflated balloon 12 is shown in solid line in Fig. 3. The inflated balloon 12 compresses the aorta and thus assists in blood displacement during diastole. When the balloon 12 is deflated it retracts to the position shown in phantom line, which allows the aorta to return to its natural shape during systole.

As Figs. 3 and 4 show, when the balloon 12 is inflated the shroud 14 restrains the balloon first portion 22, up to and including the part adjacent the flexure region 24, against outward displacement past a predetermined limit. That limit being defined by the shape of the shroud body portion 30. However, the shroud 14 does not restrain the

inward displacement of the balloon first portion 22, particularly that part at or near the flexure region 24, during deflation. This allows the balloon 12 to always retain a relatively large radius of curvature (e.g. 1.0mm) adjacent the flexure region 24, which is the part of the balloon 12 that undergoes the most deformation. This advantageously minimises stress and strain concentration in the flexure region 24, which results in a much more reliable and longer lasting balloon 18.

This is in contrast to the balloons shown in the two prior art documents mentioned previously which are restrained at a region equivalent to the flexure region for both inward and outward displacement. These balloons undergo a movement akin to pivoting or bending at their free edge. This results in high levels of stress concentration, and associated higher risk of failure, in those balloons.

Further, cycle testing of a group of actuators configured for use with sheep (and corresponding to the actuator 10 described above) were terminated after the equivalent of two years cycling without any failures. In addition, cycle testing of similar actuators configured for use with humans has achieved the equivalent of 18 months use without any failures.

The actuator 10 is also simpler, and thus cheaper, to assemble and manufacture than the prior art devices as the bushing 16 only engages with the balloon 12 in the region of their respective neck portions 40, 18, as opposed to positioning the bushing (or shell) more fully within the body portions of the balloon.

It should also be noted that the actuator 10 is designed to be applied to the outside of a blood vessel and is thus advantageously non-blood contacting as compared to the prior art devices discussed in the Background of the Invention, which are positioned within the wall of a blood vessel.

It should also be noted that the inward concavity of the balloon (when deflated) is designed to fit the arcuate ascending aorta particularly, to allow a conformal wrapping of the assembled actuator around the ascending aorta. With balloon inflation, the aortic wall is displaced in a "thumbprinting" manner, which has been shown by finite element analysis to cause minimal strain concentration in the aortic wall and also to provide maximal blood volume displacement.

In a more preferred embodiment, the balloon has in its longitudinal plane, a gentle arc of the order of radius of 150-300mm, to accommodate the slight spiral nature of the ascending aorta, to allow further conformal fitting of the assembled device.

Figs. 5 and 6 show a second embodiment of actuator 50 according to the invention. The device 50 is similar to the first embodiment and like reference numerals are used to indicate like features.

The major difference between the two embodiments is that the bushing 16 in the device 50 includes a series of internal projections 52 which serve to stop the balloon 18 being sucked into the bore 36 of the bushing during large amounts of suction/deflation. Such large amounts of suction/deflation can occur during the calibration cycle of some of the pumps suitable for use with the blood displacing device 50.

Figs. 7 and 8 show a balloon 60 for a third embodiment of actuator according to the invention. The balloon 60 is sized for adult use is but is otherwise similar to the first embodiment and like reference numerals are used to indicate like features. When viewed in plan, the first and second body portions 24 and 26 are generally elliptical in shape and have a maximum width and length of 35mm and 80mm respectively. The balloon neck portion has a diameter of approximately 10mm at its distal end 18a and approximately 26-44mm (oval in cross-section) at its proximal end 18b and a conical converging taper therebetween.

Figs. 8 to 10 show a fourth embodiment of actuator 70 according to the invention. Like features to earlier embodiments are indicated with like reference numerals. The actuator 70 utilises the balloon 60 shown in Figs. 7 and 8. The bushing 16 of the actuator 70 differs from earlier embodiments in that it is substantially hollow with a central cylindrical part 16a attached at one end to an outer flared conical part 16b. A series of radial webs 16c are provided between the central cylindrical part 16a and the flared conical part 16b. A flexible, relatively inelastic wrap 72 is provided over the balloon 60, which has an opening 72a through which the bushing 16 protrudes.

It will be appreciated by the persons skilled in the art that numerous variations and/or modifications can be made to the invention as shown in the specific embodiment without departing from the spirit or scope of the invention as broadly defined. For example, the blood displacing devices are described above in relation to extra-aortic counter-pulsation but also suitable for intra aortic counter-pulsation. In the latter the second portion of the balloon replaces a resected portion of arterial vessel, with the opening made in the resected arterial vessel being sealingly connected to the balloon adjacent the flexure region.

CLAIMS:

1. An actuator for a heart assist device, the actuator including:

an inflatable balloon having a first body portion, a second body portion and a flexure region joining the first and second body portions; and

a shroud or wrap adjacent the first body portion and having a peripheral extent at least equal to the peripheral extent of the balloon flexure region;

wherein the balloon and the shroud or wrap are shaped such that the shroud or wrap restrains a part of the balloon first body portion at or near the flexure region against displacement towards the shroud or wrap past a predetermined limit but allows unrestrained displacement away from the shroud or wrap.

2. The actuator as claimed in claim 1, wherein the balloon and the shroud are shaped such that the shroud restrains said part of the balloon first body portion at or near the flexure region against outward displacement during inflation of the balloon but allows unrestrained inward displacement during deflation.

3. The actuator as claimed in claim 1 or 2, wherein, during inward displacement, at least part of the inner surface of the balloon second body portion is able to be drawn against at least part of the inner surface of the balloon first body portion.

4. The actuator as claimed in claim 1, 2 or 3, wherein the shroud is generally inwardly concave.

5. The actuator as claimed in claim 4, wherein the shroud is elongated and elliptical.

6. The actuator as claimed in any one of the preceding claims, wherein the first body portion, second body portion and flexure region are integrally formed.

7. The actuator as claimed in claim 6, wherein the first body portion, second body portion and flexure region are integrally formed by dip moulding.

8. The actuator as claimed in any one of the preceding claims, wherein the actuator also includes a bushing adapted for connection to a motive power source.

9. The actuator as claimed in claim 8, wherein the balloon also includes a neck portion joined to the first portion, the neck portion being adapted for sealing connection with the bushing.

10. The actuator as claimed in claim 9, wherein the shroud also includes a neck portion adapted for sealing connection with the balloon neck portion.

11. An actuator for a heart assist device, the actuator including:

a bushing adapted for connection to a hydraulic or pneumatic power source; and

an inflatable balloon having a narrower neck portion adapted for sealing connection with the bushing exterior, wider first and second body portions and an arcuate flexure region joining the first and second body portions, the first body portion having a first end adjacent the neck portion and a second end adjacent the second body portion and being generally inwardly concave, the second body portion being inwardly concave when the balloon is inflated and generally outwardly concave when the balloon is deflated.

12. The actuator as claimed in claim 11, wherein the device also includes a shroud or wrap having a body portion with a peripheral extent at least equal to the peripheral extent of the balloon first and second body portions.

13. The actuator as claimed in claim 12, wherein the balloon and the shroud or wrap are shaped such that a part of the balloon first body portion at or near the flexure region is restrained against outward displacement past a predetermined limit by the shroud or wrap but unrestrained against inward displacement.

14. The actuator as claimed in claim 13, wherein during inward displacement, at least part of the inner surface of the balloon second body portion is able to be drawn directly against at least part of the inner surface of the balloon first body portion.

15. A heart assist device including:

a hydraulic or pneumatic power source; and

an actuator including:

a bushing adapted for operative connection to the motive power source;

an inflatable balloon having a narrower neck portion adapted for sealing connection with the bushing exterior, wider first and second body portions and a flexure region joining the first and second body portions, the first body portion having a first end adjacent the neck portion and a second end adjacent the second body portion and being generally inwardly concave, the second body portion being generally inwardly concave when the balloon is inflated and generally outwardly concave when the balloon is deflated; and

a shroud or wrap having a body portion with a peripheral extent at least equal to the peripheral extent of the balloon first and second body portions,

wherein the balloon and the shroud are shaped such that a part of the balloon first body portion at or near the flexure region is restrained against outward displacement by the shroud past a predetermined limit but unrestrained against inward displacement.

16. The device as claimed in claim 15, wherein, during inward

displacement, at least part of the inner surface of the balloon second body portion is able to be drawn against at least part of the inner surface of the balloon first body portion.

17. The device as claimed in claim 15 or 16, wherein the balloon and shroud are shaped such that substantially all of the balloon first body portion is restrained against outward displacement by the shroud and unrestrained against inward displacement.

18. The device as claimed in claim 15, 16 or 17, wherein the heart assist device is configured for extra-aortic counter-pulsation and the balloon is positioned on the exterior of an arterial vessel.

19. The device as claimed in claim 15, 16 or 17, wherein the heart assist device is configured for use as an interposition graft in which the device replaces a completely resected section of the aorta.

20. The device as claimed in claim 15, 16 or 17, wherein the heart assist device is configured for use as an aortic patch in which an aperture is formed in the aorta which is filled with the heart assist device.

21. The device as claimed in any one of claims 15 to 20, wherein, when the balloon is inflated, the flexure region has a radius of curvature of at least 0.1 mm.

22. The device as claimed in claim 21, wherein, when the balloon is inflated, the flexure region has a radius of curvature of approximately 1.0 mm.

23. The device as claimed in claim 22, wherein, when the balloon is inflated, the flexure region has a radius of curvature of approximately 3.0 mm.

24. The device as claimed in any one of claims 15 to 23, wherein the ratio of the diameter of the balloon neck portion to the balloon flexure region is no more than approximately 4:1.

25. The device as claimed in any one of claims 15 to 23, wherein the ratio of the diameter of the balloon neck portion to the balloon flexure region is approximately 3:1

26. The device as claimed in any one of claims 15 to 23, wherein the ratio of the diameter of the balloon neck portion to the balloon flexure region is approximately 2:1

27. The device as claimed in any one of claims 15 to 26, wherein the bushing has an inlet/outlet bore.

28. The device as claimed in claim 27, wherein the bore also includes one or more internal restrictions adapted to prevent suction of the balloon into the bore.

29. The device as claimed in anyone of claims 15 to 28, wherein the balloon is formed from silicone, polyurethane or a polyurethane-polysiloxane block co-polymer.

30. The device as claimed in any one of claims 15 to 29, wherein the balloon is formed by mandrel dipping.

31. The device as claimed in any one of claims 15 to 30, wherein the balloon is formed by dipping a suitably shaped mandrel into the polymer and allowing a thin coating of the polymer to cure on the mandrel.

32. The device as claimed in claim 31, wherein the balloon is made of 2 to 4 coatings of the polymer.

33. The device as claimed in claim 32, wherein the balloon a total thickness of 150-300 microns.

34. The device as claimed in any one of claims 15 to 33, wherein the balloon neck portion is a snug sealing fit over the bushing exterior.

35. The device as claimed in claim 34, wherein the shroud or wrap has a neck portion that is a snug sealing fit over the balloon neck portion.

36. The device as claimed in claim 35, wherein the bushing has a slightly tapered neck portion adapted for engagement with the balloon neck portion.

37. The device as claimed in claim 36, wherein the bushing neck portion has a converging taper in the direction of the balloon.

38. The device as claimed in any one of claims 15 to 37, wherein the balloon is held in place on the aorta by a flexible wrap which extends about the aorta and bears against the first body portion of the balloon or a shroud mounted thereon.

39. The device as claimed in claim 38, wherein the flexible wrap is shaped to fit the second body portion of the balloon.

40. The device as claimed in claim 39, wherein the flexible wrap is also shaped to fit the neck portion.

41. The device as claimed in claim 38, 39 or 40, wherein the flexible wrap is inelastic or slightly elastic so that its stretch and flexibility characteristics substantially match those of the native aorta.

42. A flexible inflatable balloon for a blood displacing heart assist device, the balloon including:

a neck portion having first and second ends;

a substantially annular first body portion connected at its inner periphery to the neck portion second end; and

a substantially oval or circular second body portion connected at its outer periphery to the outer periphery of the first body portion,

the outer peripheries of the first and second body portions are connected along an annular inwardly concavely curved flexure portion adapted to maintain a radius of curvature during movement of the second body portion between inwardly concave and outwardly concave during deflation and inflation of the balloon respectively.

43. The balloon as claimed in claim 42, wherein the balloon is formed as a single piece.

44. The balloon as claimed in claim 42 or 43, and further including a shroud adapted to overlie and abut the annular first body portion of the balloon.

45. The balloon as claimed in claim 44, wherein the shroud is shaped such that the shroud restrains said portion of the balloon at or near the flexure region against outward displacement during inflation of the balloon but allows unrestrained inward displacement during deflation.

46. The balloon as claimed in claim 44 or 45, wherein the shroud is generally inwardly concave

47. The balloon as claimed in claim 46, wherein the shroud is elongated, and elliptical.

48. The balloon as claimed in any one of claims 44 to 46, wherein the shroud also includes a neck portion adapted for sealing connection with the balloon neck portion.

49. The balloon as claimed in claim 48, wherein the shroud is adapted to facilitate bonding of a wrap to the first body portion of the balloon.

50. The balloon as claimed in any one of claims 42 to 49, and further including a bushing adapted for connection to a hydraulic or pneumatic power source.

51. The balloon as claimed in claim 50, wherein the bushing is formed with internal restrictions such as flutes, ribs, or secondary lumens to prevent the balloon being sucked into the bushing during deflation of the balloon.

52. The balloon as claimed in claim 50or 51, wherein the neck portion of the balloon is adapted for sealing connection with the bushing.

53. The balloon as claimed in claim 50, 51 or 52, wherein the bushing has a taper adapting the relatively large diameter of the neck of the balloon to the relatively

small diameter of a hydraulic or pneumatic fluid line connecting the balloon to a power source.

54. The balloon as claimed in claim 53, wherein this taper is elongated to enhance the flexibility of the bushing along its central axis.

55. The balloon as claimed in any one of claims 42 to 54, wherein the balloon has in its longitudinal plane, a gentle arc of the order of radius of 150-300mm.

56. An actuator for a heart assist device, the actuator including:

a flexible inflatable balloon having a neck portion connected at one end to a bulbous body portion having a first side and a second side; and

a substantially inelastic shroud or wrap having a flared portion that extends over the adjacent first side of the balloon bulbous portion,

wherein, during deflation, the second side of the bulbous body portion is able to be drawn against the first side of the bulbous body portion.

57. The actuator as claimed in claim 56, wherein the shroud or wrap supports the first side of the balloon bulbous portion against substantial movement whilst the second side of the balloon bulbous portion is free to move during inflation and deflation.

58. A method of providing extra-aortic heart assistance using the actuator claimed in any one of claims 1 to 10, 11 to 14 or 56 or 57, or the heart assist device claimed in any one of claims 15 to 41, or the balloon claimed in any one of claims 40 to 51, the method including mounting the balloon second body portion adjacent the exterior of an arterial vessel.

59. A method of providing intra-aortic heart assistance using the actuator claimed in any one of claims 1 to 10, 11 to 14 or 56 or 57, or the heart assist device claimed in any one of claims 15 to 41, the method including resecting a portion of an arterial vessel and mounting the balloon with the balloon second body portion sealingly replacing the resected arterial portion.

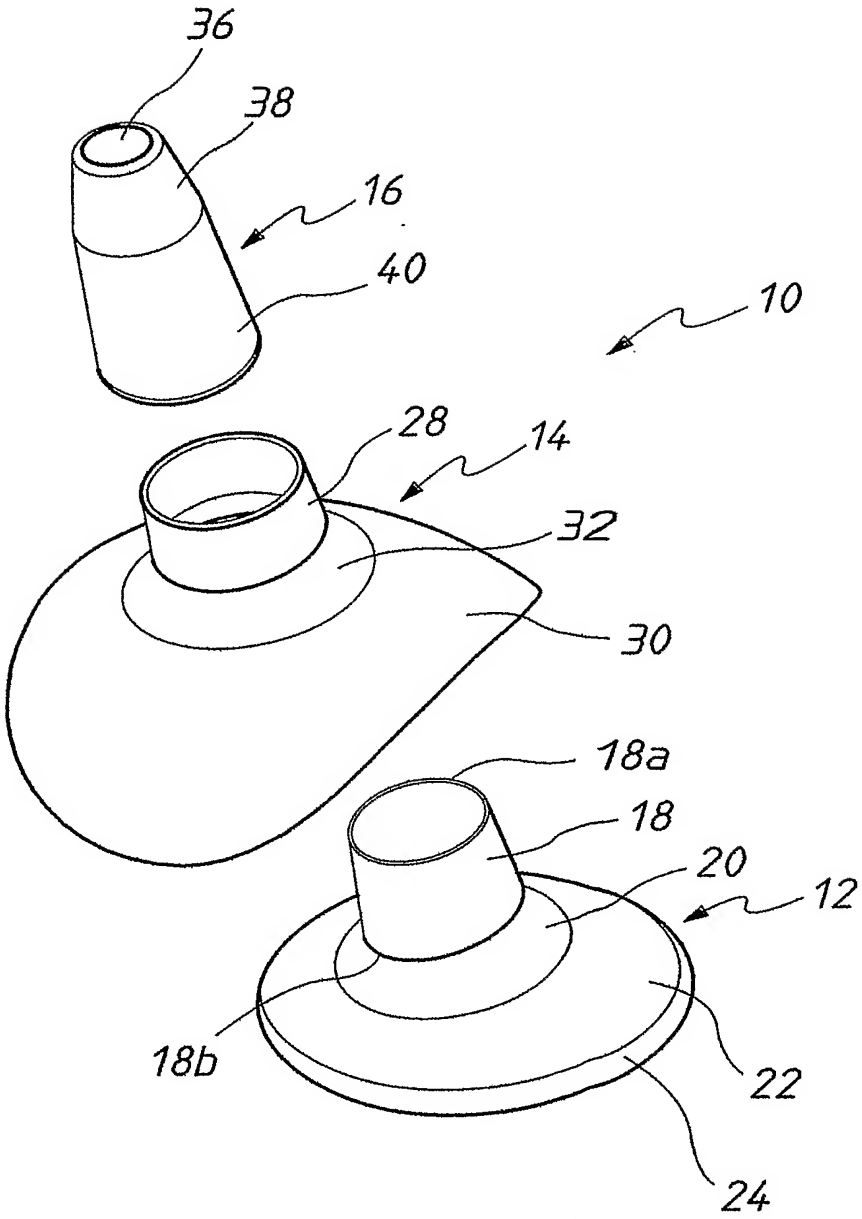


FIG. 1

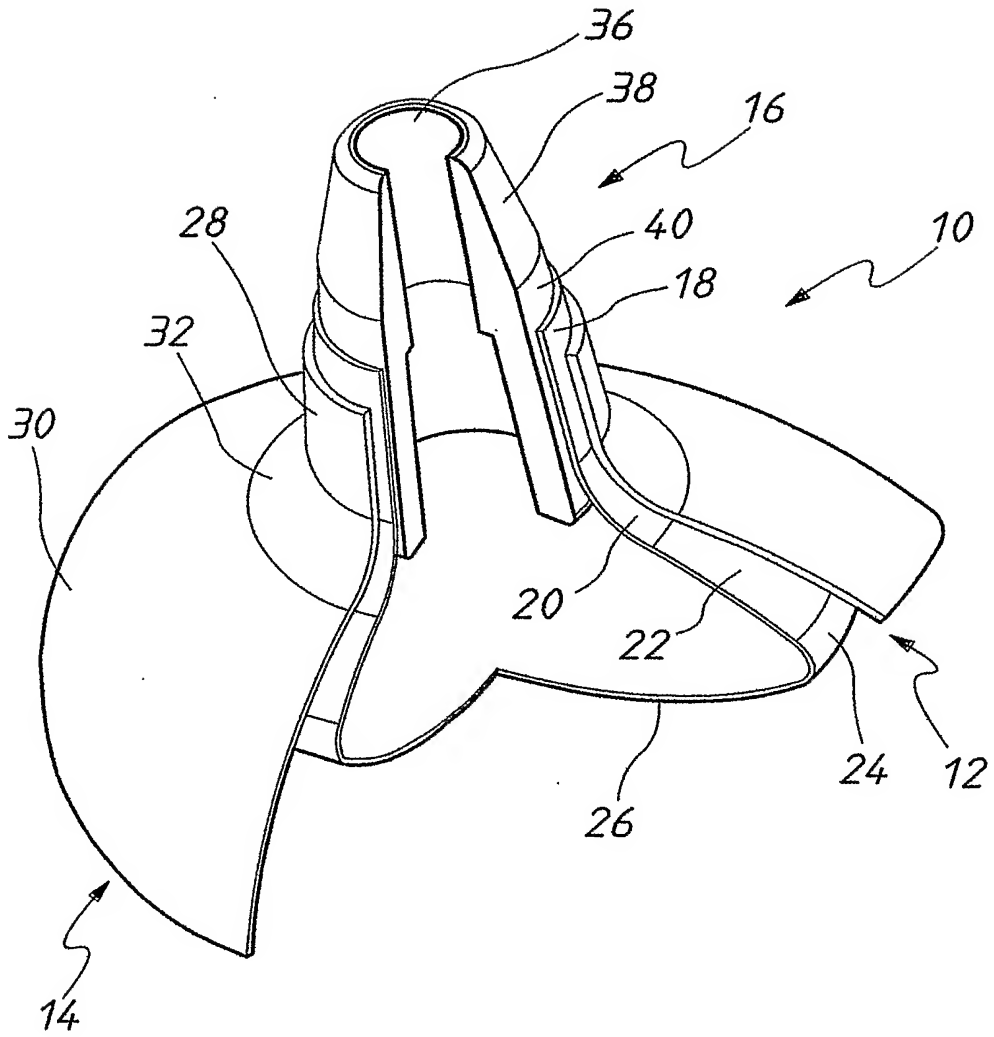


FIG.2

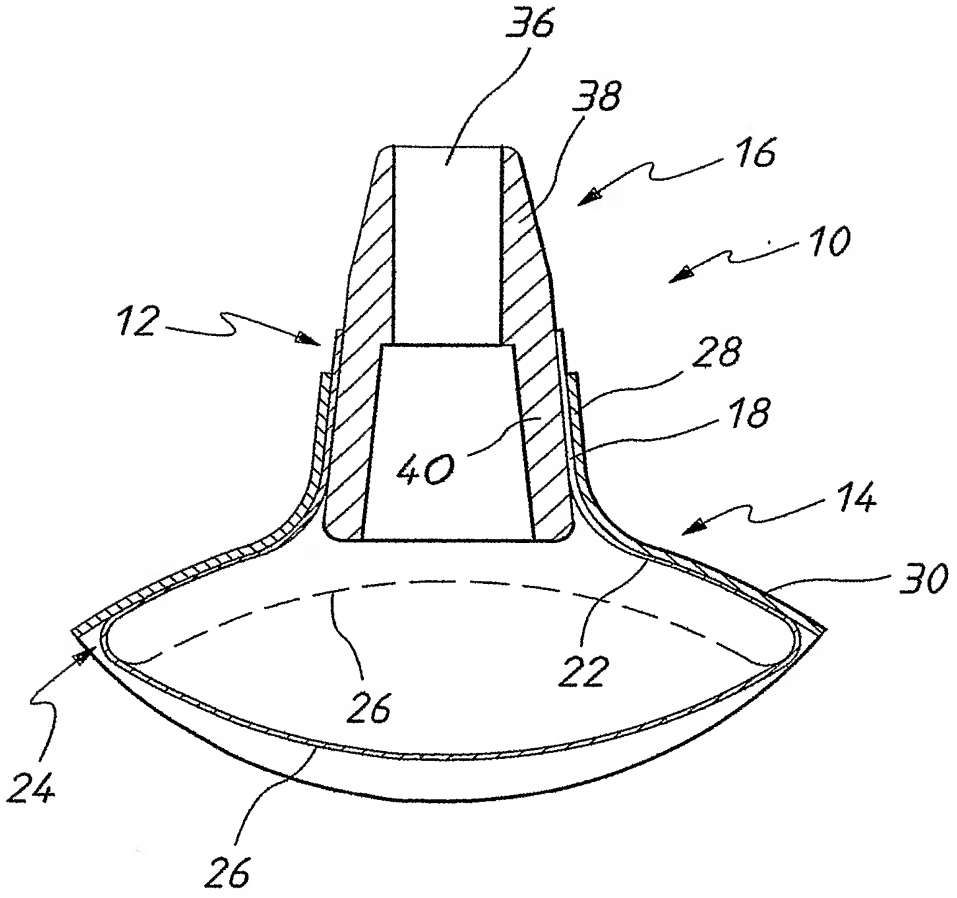


FIG.3

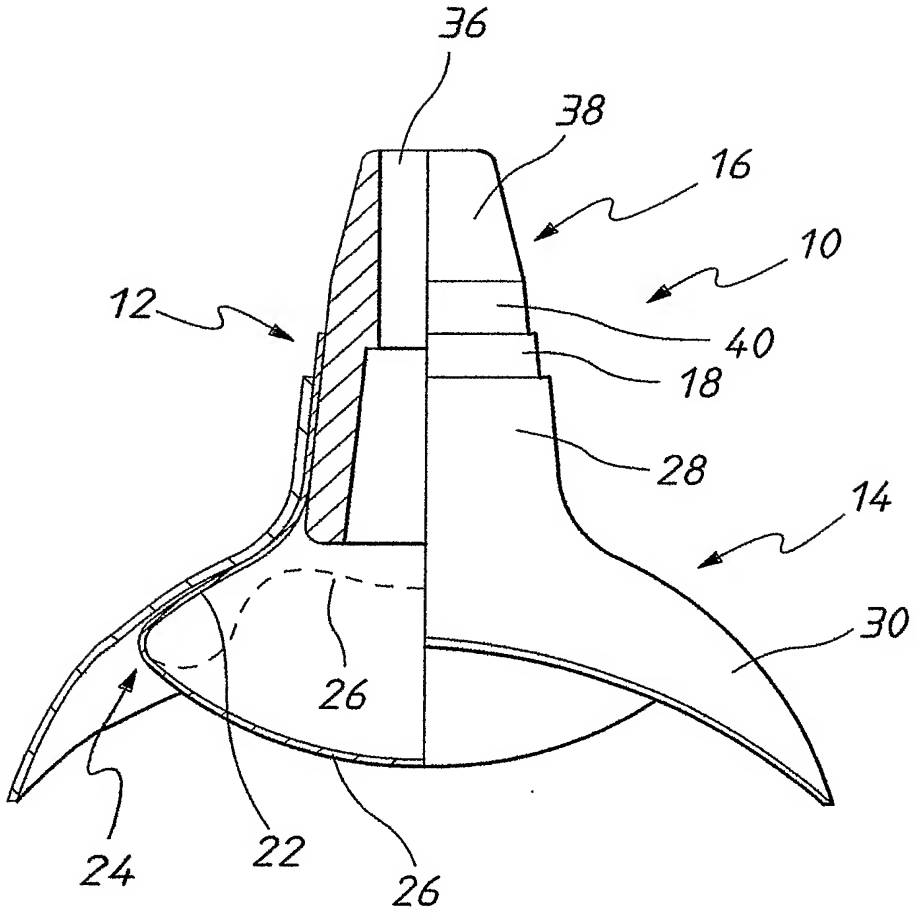


FIG.4

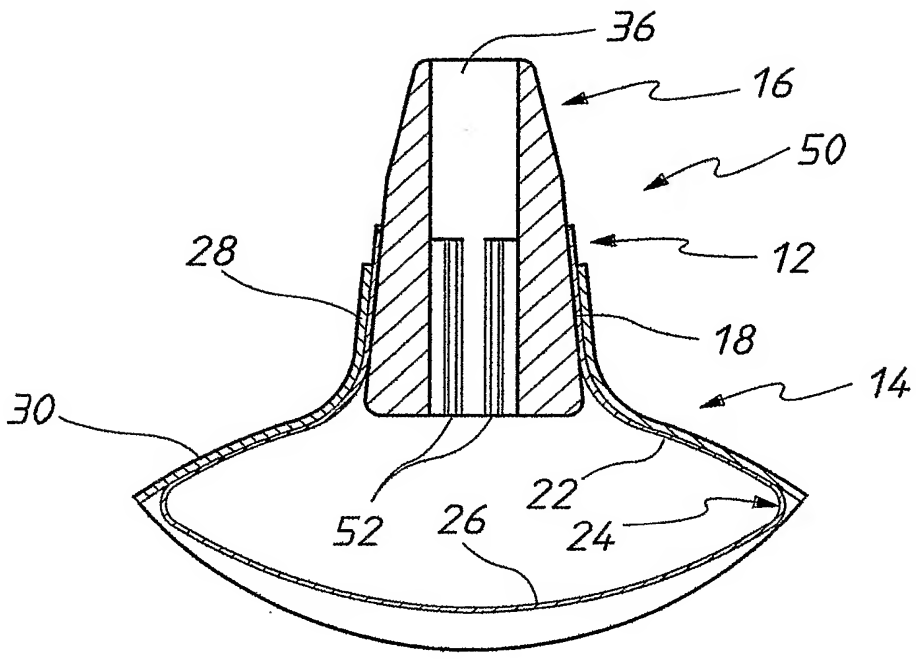


FIG.5

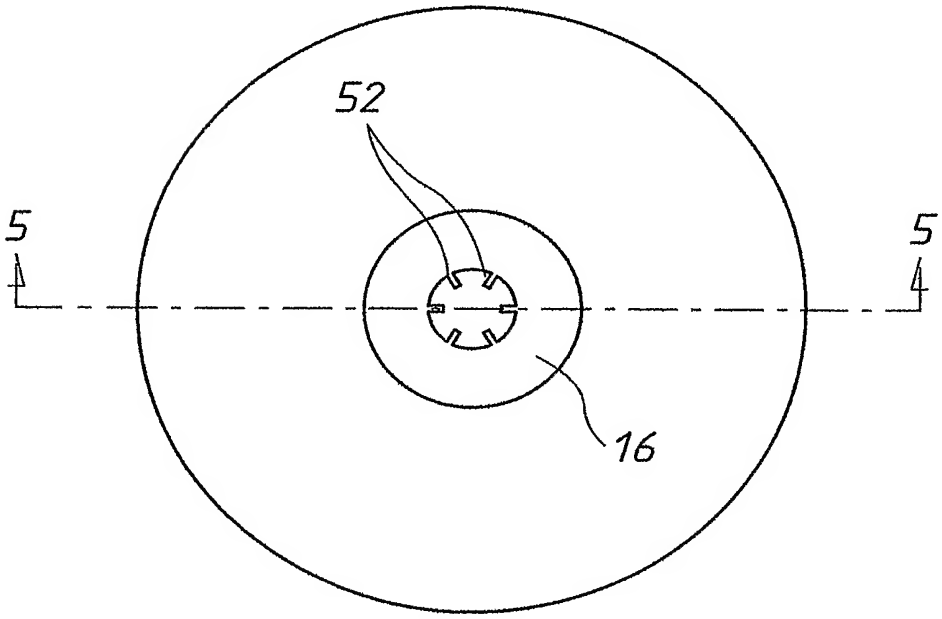


FIG.6

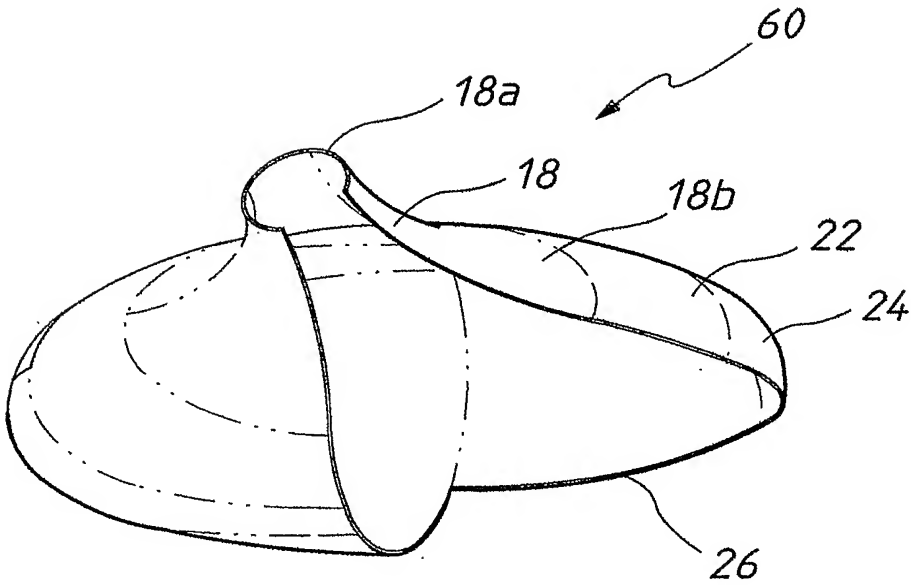


FIG.7

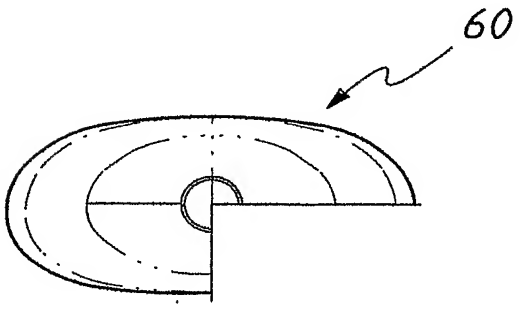


FIG.8

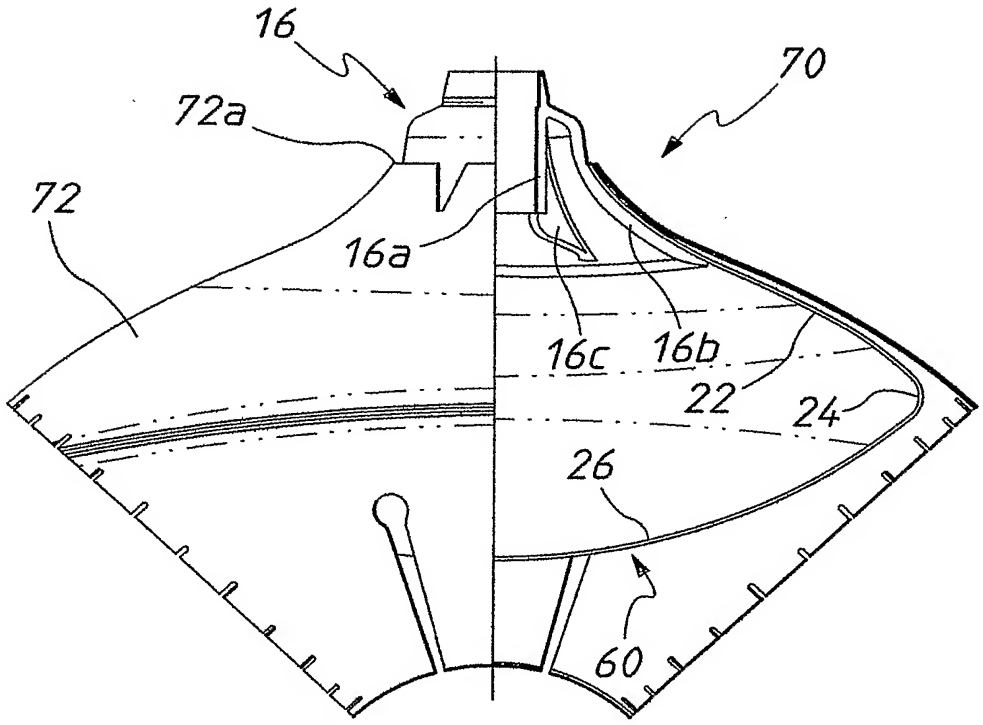


FIG. 9

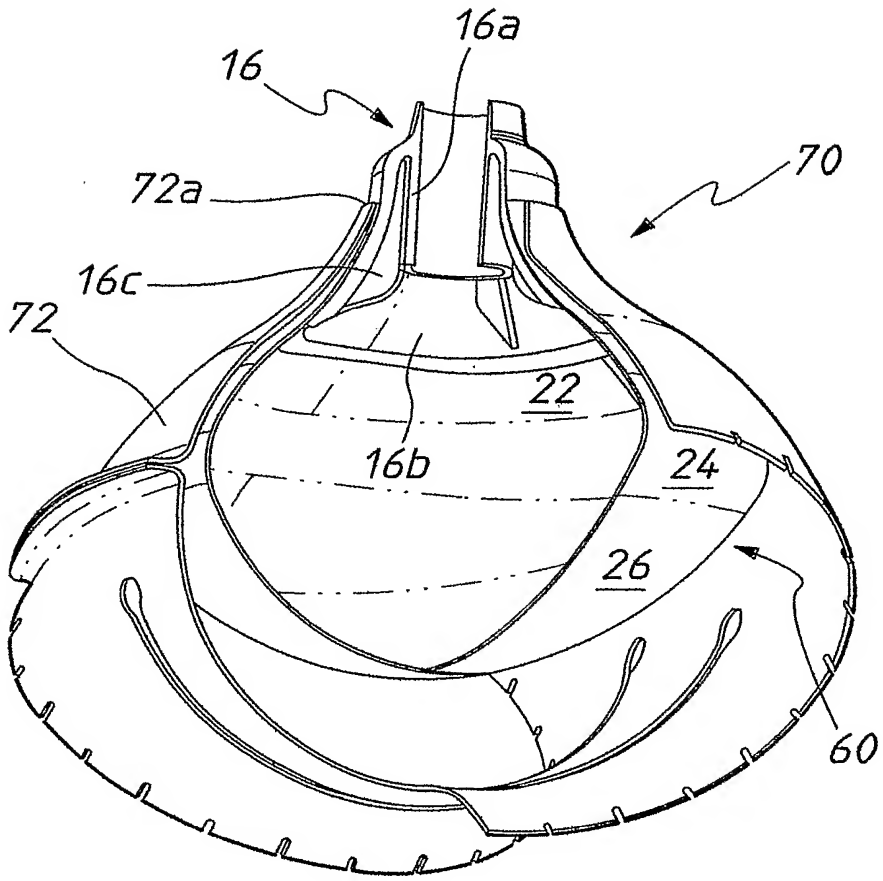


FIG. 10

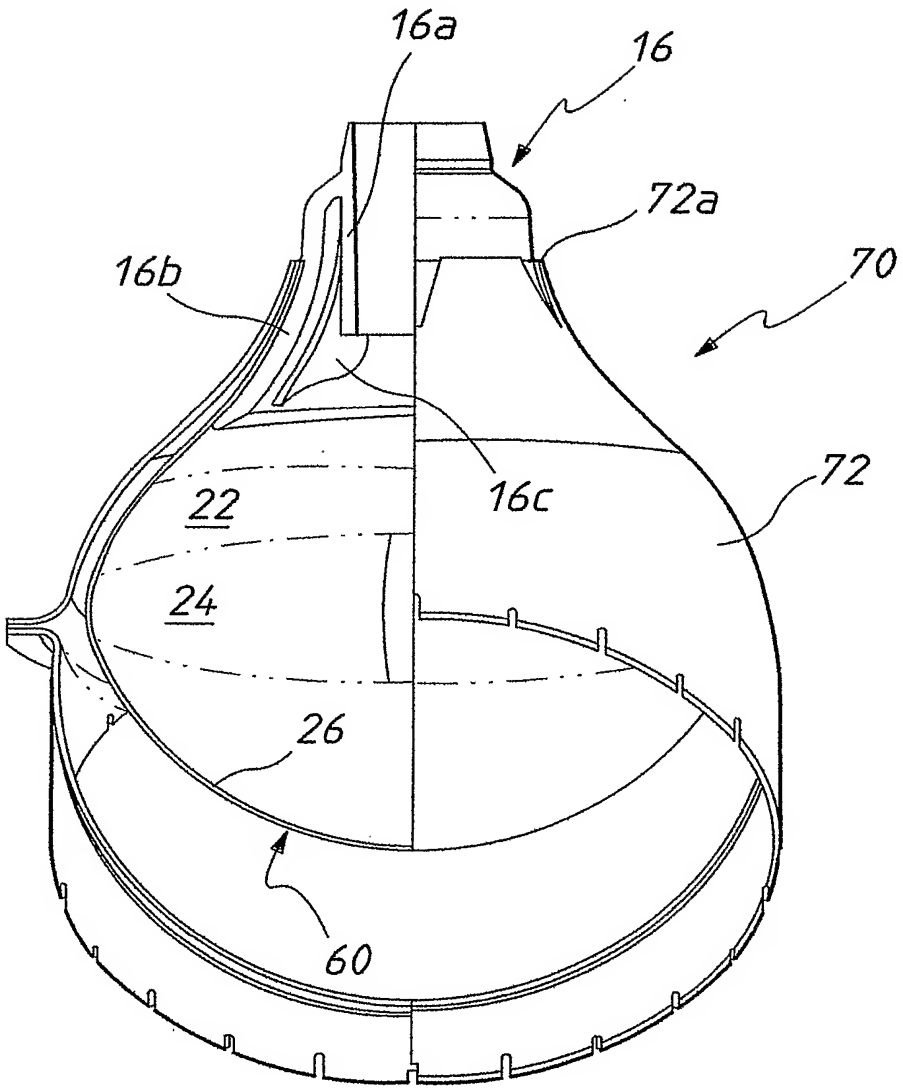


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/001487

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 1/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI IPC A61M 1/10/- A61M 1/12/- + keywords (VAD, aorta, artery, cardi, ventric, assist, pump, actuator, balloon, bladder, shroud, wrap, limit, restrain and similar terms)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 2002/024255 A1 (SUNSHINE HEART COMPANY PTY LTD) 28 March 2002 Pages 10-15, figures.	1-4, 6, 56, 57 15-25, 27, 29, 34, 38
X Y	US 4051840 A (KANTROWITZ et al) 4 October 1977 Whole document	1-9 15, 17, 18, 29, 38
X	WO 2000/076288 A2 (SUNSHINE HEART COMPANY PTY LTD) 21 December 2000 Pages 11-16, figures 8-10	1-6, 56, 57
X	US 4881939 A (NEWMAN) 21 November 1989 Columns 3-5, figures 8a-8b and 13a-13c	1-4, 6

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 December 2004	27 JAN 2005
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **Sue Thomas** Telephone No : (02) 6283 2454

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/001487

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2001/013974 A2 (L.VAD TECHNOLOGY INC) 1 March 2001 Pages 8-14 and figures.	3-7, 11-25,27, 29, 38
X	US 4630597 A (KANTROWITZ et al) 23 December 1986 Whole document	42, 43, 50, 52-55
Y		4-7, 11-25, 27, 29, 34, 38
X	FR 2645739 A1 (VM TECH SA) 19 October 1990 Whole document	1-5,8
Y		11-14
X	WO 2002/024254 A2 (IMPERIAL COLLEGE INNOVATIONS LTD) 28 March 2002 Pages 14, 15 and figures	1-4, 6, 56, 57
	US 4630597 (column 3) provides the feature of bushing to be read with Y documents WO 2002/024255, US 4051840, WO 2001/013974, FR 2645739 and US 4630597. WO 2001/013974 is to be read with WO 2002/024255 for claims 19, 20, 27, 38.	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/001487

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: **58, 59**
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See extra sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

The International Searching Authority found multiple inventions in the present application as follows:

Group 1: Claims 1-10, 56, 57 define an actuator for a heart assist device having first and second body portions in which the first special technical features is a shroud or wrap

Group 2: Claims 11-14 define an actuator for a heart assist device having balloon first and second body portions in which the second special technical feature is a bushing

Group 3: Claims 15-41 define a heart assist device having balloon first and second body portions and both the first and second special technical features, and could be considered with either group 1 or group 2. It is noted, however, that group 1 does not include the second special feature and group 2 does not include the first special feature.

Group 4: Claims 42-55 define a flexible inflatable balloon for a blood displacing heart assist device having first and second body portions in which the third special technical feature is a connecting body portion which is adapted to maintain a radius of curvature during movement of the second body portion between deflation and inflation of the balloon.

Group 5: The scope of claim 58 is unclear because of its multiple dependencies.

Group 6: The scope of claim 59 is unclear because of its multiple dependencies.

The features held in common by the claims are a balloon having first and second body portions which does not provide novelty or inventive step for the application because these features are provided by US 4881939, WO 2002/024255 and WO 2001/013974 as examples only amongst other citations.

No other feature which could provide novelty or inventive step for the application as a whole is found common to all the groups of claims.

Consequently the application lacks unity of invention.

Information on patent family members

International application No.
PCT/AU2004/001487

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	2002/024255	AU	91488/01	EP	1318848	US	2004073080
US	4051840	NIL					
WO	2000/076288	AU	50548/00	BR	0011464	CA	2375962
		EP	1185319	US	2004167376		
US	4881939	NIL					
US	4630597	NIL					
WO	2001/013974	AU	69241/00	CA	2382671	EP	1207921
FR	2645739	NIL					
WO	2002/024254	AU	90088/01	BR	0114087	CA	2421812
		EP	1379294	US	2003233023		

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 May 2005 (19.05.2005)

PCT

(10) International Publication Number
WO 2005/044338 A1

(51) International Patent Classification[7]: A61M 1/12

(21) International Application Number:
PCT/AU2004/001487

(22) International Filing Date: 28 October 2004 (28.10.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2003906212 11 November 2003 (11.11.2003) AU

(71) Applicant *(for all designated States except US)*: **SUNSHINE HEART COMPANY PTY LTD** [AU/AU]; 2A River Street, Birchgrove, NSW 2041 (AU).

(72) Inventor; and

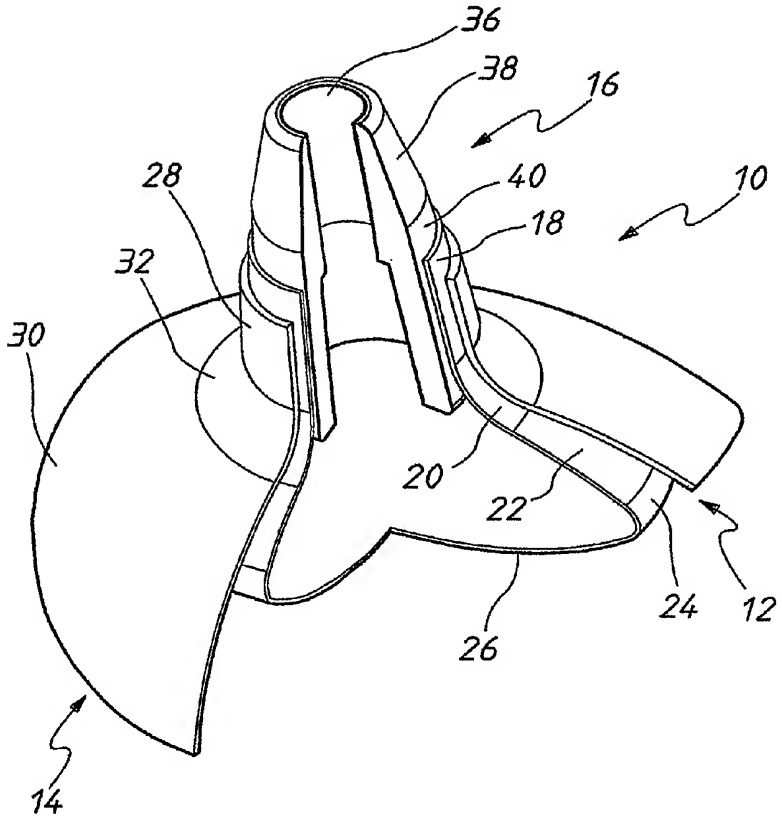
(75) Inventor/Applicant *(for US only)*: **MILLER, Scott, Hugh** [US/AU]; 35/10 Darley Road, Manly, NSW 2095 (AU).

(74) Agent: **SPRUSON & FERGUSON**; GPO BOX 3898, Sydney, NSW 2001 (AU).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

[Continued on next page]

(54) Title: ACTUATOR FOR A HEART ASSIST DEVICE



(57) Abstract: An actuator (10) for a heart assist device. The actuator (10) includes an inflatable balloon (12) and a shroud or wrap (14). The inflatable balloon (12) has a first body portion (22), a second body portion (26) and a flexure region joining (24) the first (22) and second (26) body portions. The shroud or wrap (14) is positioned adjacent the first body portion (24) and has a peripheral extent at least equal to the peripheral extent of the balloon flexure region (24). The balloon (12) and the shroud or wrap (14) are shaped such that the shroud or wrap (14) restrains a part of the balloon first body portion (22) at or near the flexure region (24) against displacement towards the shroud or wrap (outward displacement) past a predetermined limit but allows unrestrained displacement away from the shroud or wrap (inward displacement).

WO 2005/044338 A1

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

(48) Date of publication of this corrected version:
28 July 2005

(15) Information about Correction:
see PCT Gazette No. 30/2005 of 28 July 2005, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.